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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/982,474

10/17/2001

Wilhelmus Theodorus Antonius Maria De Laat

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06/14/2006

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EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/982,474

Applicant(s)

DE LAAT ET AL.

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 52-63 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-63 and 65-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 03/23/2006 has been entered.

Examiner has acknowledged that claims 1-37 have been cancelled and claims 38-51 and 64 have been withdrawn from considerations

Claims 52-63 and 65-68 will be examined on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-53 and 65-68 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recite the limitation "the carbon source" and "the nitrogen source."

There is insufficient antecedent basis for this limitation in the claims.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-63 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan (US 4164445) in view of Microbiology, fourth edition, Pelezar, Reid, and Chan pages 853-856.

Although unclear as drafted, applicant claims a process for the production of Beta-Lactam (i.e. Penicillin V and/or Adipoyl-7-ADCA) comprising the steps of fermenting on a volume scale of at least 10 m<sup>3</sup> a microbial strain (e.g. *Pencillium chrysogenum*) that produces a Beta-Lactam in a fermentation medium wherein the fermentation medium is a carbohydrate, glycerol, a vegetable oil or a hydrocarbon and wherein the fermentation medium is urea, ammonia, nitrate, an ammonium salt or an amino acid and wherein said fermentation medium contains an amount of complex carbon and/or nitrogen source that is at most about 10% of the total amount of carbon and/or nitrogen, and recovering the Beta-Lactam from the fermentation medium is apparently claimed.

Sheehan et al. (see, e.g. abstract, column 1 lines 5-19, column 2 lines 14-18 and example 1 and example 2) teach a process for the production of Beta-Lactam (i.e. Penicillin V) comprising the steps of fermenting a microbial strain (e.g. *Pencillium chrysogenum*) that produces a Beta-Lactam in a fermentation medium wherein the

fermentation medium is a carbohydrate (i.e. glucose) or vegetable oil (i.e. soybean oil) and wherein the fermentation medium is an ammonium salt.

(Please note: Since applicant claims a fermentation medium that does not exclude other ingredients such as ethanol being contained within the applicant's claimed fermentation, ethanol can be contained within applicant's claimed fermentation medium of applicant's claimed specific carbon and/or nitrogen sources to aid in producing the claimed penicillin V, see, e.g. Sheehan's example 2).

Sheehan et al. do not teach the process of the production of Beta-Lactam comprising the steps of fermenting on a volume scale of at least 10m<sup>3</sup>, the claimed process which produces adipoyl-7-ADCA, the amount of complex and/or nitrogen is at most about 10 %, and recovering the Beta-Lactam from the fermentation medium.

Microbiology, pages 853-856, teaches that a Beta-Lactam (penicillin) was the first antibiotic to be produced industrially utilizing a similar standard chemically defined medium as the claimed invention's chemically defined medium (see, especially, e.g. page 855-856, the steps).

It would have been obvious to one of ordinary skill in the art of creating the claimed invention to modify Sheehan et al.'s teaching and to include the beneficial teachings of Microbiology because the above two combined reference teachings utilizing the same process steps would produce an improved process for the production of Beta-Lactam at an industrialized scale. The adjustment of these and other conventional working conditions (i.e. fed-batch fermentation, the amount of complex and/or nitrogen is at most about 10 %, recovering the Beta-Lactam from the

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fermentation medium and the substitution of one Penicillin for the another Penicillin (i.e. the substitution of Penicillin V for adipoyl-7-ADCA) utilizing the same claimed steps)), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**CHRISTOPHER R. TATE**  
**PRIMARY EXAMINER**